U.S.S.N. 08/924,994 FILED: SEPTEMBER 5, 1998 AMENDMENT

In the Claims

1. (Three times amended) A method for determining the level of an apolipoprotein in [saliva] the serum of an individual based on levels of the apolipoprotein in the individual's saliva comprising

obtaining a saliva sample from an individual,

reacting the apolipoproteins in [a] the saliva sample with antibodies immunoreactive with [the apolipoprotein] one or more of the apolipoproteins, wherein the antibodies are in a quantitative assay which measures the amount or concentration of bound complexes between apolipoproteins and the antibodies immunoreactive therewith,

[using a quantitative assay kit comprising means for collection of saliva, and antibodies immunoreactive with an apolipoprotein and means for comparing the levels of the apolipoproteins in the saliva with the levels in serum,]

[detecting] <u>determining</u> the amount of <u>apolipoproteins</u> in the serum of the individual by <u>comparing the</u> immunoreactivity between the antibodies and apolipoproteins in the saliva sample [as determined by the quantitative assay] <u>by reference to</u> [, and

comparing the amount of determined immunoreactivity with] standards of known amounts of apolipoproteins in saliva and serum [reacted with the antibodies to determine the level of apolipoproteins in the saliva sample].

2. (Amended) The method of claim 1 wherein the apolipoprotein is selected from the group consisting of Apo A, Apo B, Apo C, and Apo E[, and components thereof].

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- 10. (twice amended) The method of claim 1 [further comprising collecting] wherein the saliva sample is collected into a device which filters out mucopolysaccharides and which comprises the antibodies immunoreactive with one or more of the apolipoproteins in the saliva sample.
- 12. (amended) An assay device or kit for determining the amount of apolipoprotein in a saliva sample comprising

means for collection of saliva, [and]

antibodies immunoreactive with [an apolipoprotein] one or more apolipoproteins, wherein the antibodies are in a quantitative assay which measures the amount or concentration of bound complexes between apolipoproteins and the antibodies immunoreactive therewith [for use in a quantitative assay], and

[means for comparing the levels of the apolipoproteins in the saliva with the levels in serum] standards of known amounts of apolipoproteins in saliva and serum.

- 14. (amended) The assay device or kit of claim 12 wherein the antibodies are reactive with apolipoprotein selected from the group consisting of Apo A, Apo B, Apo C, and Apo E[, and components thereof].
- 20. (Twice amended) A method for quantitating the amount of lipoprotein or cholesterol in saliva or determining the presence of lipid disorders or risk of cardiovascular disease from a saliva sample comprising

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- [(a) reacting the apolipoproteins in a saliva sample with antibodies specifically immunoreactive with apolipoprotein selected from the group consisting of Apo A, Apo B, Apo C, and Apo E[, and components thereof] in a quantitative assay,
- (b) determining the amount of immunoreaction between the antibodies and the apolipoproteins in the saliva sample, and
- (c) comparing the amount of immunoreaction determined in step b with the amount of immunoreaction of the antibodies immunoreactive with the apolipoprotein in the saliva sample]

 <u>obtaining a saliva sample from an individual.</u>

reacting the apolipoproteins in the saliva sample with antibodies immunoreactive with one or more of the apolipoproteins, wherein the antibodies are in a quantitative assay which measures the amount or concentration of bound complexes between apolipoproteins and the antibodies immunoreactive therewith.

determining the amount of apolipoproteins in the serum of the individual by comparing
the immunoreactivity between the antibodies and apolipoproteins in the saliva sample by
reference to standards of known amounts of apolipoproteins in saliva and serum from normal or
at risk individuals.

21. (twice amended) The method of claim 1 further comprising,

correlating the levels of <u>one or more lipoproteins selected from the group consisting of</u>
[HDL] <u>high density lipoprotein</u> [and/or] <u>and</u> [LDL] <u>low density lipoprotein</u>, in the serum with the levels of [apolipoproteins] <u>apolipoprotein subtypes</u> in the serum,